

Serial No. 09/926,712

Response to Office Action of July 30, 2003

REMARKS

Claim 1 has been limited in respect of the definitions of R_2 , -X-X-, Y, Cy and L by incorporating Claims 5, 7 and 11, by limiting the definition of R_2 to the values given in (i) and (ii), and by limiting the definition of Cy to a homocyclic (i.e. non-heterocyclic) ring). In addition, to expedite allowance of the application, the value of cyano as a possible substituent at the 3 and/or 4 position on R_2 when R_2 is phenyl has been deleted from Claim 1. The Examiner will recall from end of Applicant's Information Disclosure Statement that compounds corresponding with formula (I) in Claim 1 in which R_2 represents phenyl substituted at the 3 position by cyano have been disclosed as intermediates to m-benzamidine compounds in WO 99/11658.

Consequential amendments have been made in the other claims.

New claims 42 and 43 have been added. These new claims are directed to the species of Examples 35, 63 and 73 and their physiologically acceptable salts, and to pharmaceutical compositions containing these species. The three species and their salts are identified as preferred at page 51, lines 6 to 8 of the description:

Applicants reserve the right to pursue claims to any originally disclosed subject matter in a continuation or divisional application.

RESTRICTION UNDER 35 U.S.C. § 121

The Examiner has requested that the application be restricted to one of two hundred and sixteen inventions, as defined by the Examiner in the Office Action.

Applicants hereby elect to prosecute the invention of Group (XIV). However, Applicants must traverse the restriction requirement as presented for reasons including

Serial No. 09/926,712
Response to Office Action of July 30, 2003

those expressed below and request the Examiner to reconsider and reformulate any required restriction.

As an initial matter, it is believed the Examiner has failed to follow the PCT in the manner of defining the restriction requirement. The requirements of 37 C.F.R. §§ 1.499 and 1.475 are embodiments of the PCT as set out in Rule 13 of the treaty and Section 206 of the Administrative Instructions. Section 206 instructs that the requirement of unity of invention shall be made in accord with Annex B. Annex B (f) is particularly relevant to the consideration. It is believed that defining restriction groups by defining, *per se*, the possible combinations of the defined variables for a compound of formula I (and creating artificial groups not disclosed in the specification for certain values) is not a method of defining unity of invention under 37 CFR § 1.475(a) in accordance with Annex B of the PCT Administrative Instructions. This methodology completely overlooks the requirement of consideration of special technical features that define a contribution which each of the defined inventions, considered as a whole, makes over the prior art.

Further, Applicants respectfully submit that the inventions defined in the office action were made by the Examiner, and are not inventions for which they are seeking protection. In particular, Applicants respectfully submit that the Examiner's definitions contain selections of values for R_2 , each X, Y, Cy, L and $L_p(D)$, that have not been presented for examination in any claim, nor described in the specification. It would therefore not be appropriate for Applicants to limit the claims as suggested by the Examiner (37 C.F.R. § 1.121).

In addition, it seems that the Examiner has misperceived the definitions of "L" and "Lp." In some instances, the definitions seem not to provide clearly for the

Serial No. 09/926,712
Response to Office Action of May 30, 2003

values of the invention. In other instances, definitions of restriction groups have been formed which are not distinct because there is resulting overlap in the definitions. (As discussed below, Applicants are attempting to ameliorate these matters by amendment.) Also, in certain definitions created for "Lp," such as "Lp is a bicyclic or tricyclic heterocyclic ring containing N as heteroatom," it is not entirely clear whether the restriction group is meant to define only fused ring systems or to include linked rings.

Thus, for example, the pending Claim 1 (prior to amendment) includes the definition:

"L is an organic linker group containing 1 to 5 backbone atoms selected from C, N, O and S, or a branched alkyl or cyclic group;"

In restriction groups there are definitions "L is C," and "L is N, O or S," which do not comport with this definition or the more specific embodiments of the description and dependent claims. Further, the definitions in Claim 1 of (i), (ii) and (iii) are composite definitions which are definitions of "-L-Lp(D)_n" in which the values of "L" may be considered, respectively, CO, CH₂NHCO and "a cyclic group" as defined. Thus, (i) has an overlap in definition with a group in which "L" is defined as CO and "Lp" for "-L-Lp(D)_n" is a substituted pyrrolidino or piperidino group in which the substitution meets the definition in (i). Similarly, (ii) has an overlap in definition with a group in which "L" is defined as CH₂NHCO and "Lp" is phenyl (which may bear certain substituents). In (iii) the value of "Lp" is (CH₂)_nR_n, which seems not to be included in any restriction group. In the amended claims, these issues are addressed by introduction of the particular values defined for "L" in dependent claims. In

Serial No. 09/926,712
Response to Office Action of July 30, 2003

certain cases [e.g. for CO , $\text{CO}(\text{CH}_2)_m$, $(\text{CH}_2)_m\text{CO}$], it is noted that there is redundancy in the definitions when $m=0$.

Applicants are providing amended claims limited to a scope that is believed to be supported by the original disclosure and can be searched without undue burden. It is believed that the claims define subject matter that is novel and non-obvious over all of the references of record in this application. Further, the elected species, discussed below, provides a basis for formation of the genus.

ELECTION OF SPECIES UNDER 37 C.F.R. § 1.141

The Examiner has invited the Applicants to elect a single species for examination under 37 C.F.R. § 1.141.

Applicants hereby elect the species of Example 35.

The species of Example 35 corresponds with formula (I) in Claim 1 wherein R is 4-chloro-3-aminophenyl, X-X is CONH, Y is CH (and is in the D-configuration), Cy is phenyl, L is CO and Ip(D)_n is 4-(4-fluoro-2-methylsulphonyl)phenyl-piperazinyl.

Currently Claims 1, 6, 8, 9, 10, 12, 19, 20, 21, 22, 27, 28, 29, 32, 34, 35, 36, 37, 38, 39, 41, 42 and 43 read on the elected species.

FUTURE COMMUNICATION BY TELEPHONE

If the Examiner wishes to speak by telephone with the undersigned in the future, the undersigned can be contacted by e-mail at martinahay@martin-a-hay.com, and would be pleased to telephone the Examiner in response. Alternatively, the Examiner can contact Linda McDonald at (317) 433 7140 and leave a message, which will be forwarded to the undersigned.

Serial No. 09/926,712
Response to Office Action of July 30, 2003

CONCLUSION

In response to the restriction and election of species requirements made by the Examiner, Applicants have elected to prosecute the invention of Group XIV and the species of Example 35. Applicants have made the election with traverse, because the restriction groups proposed by the Examiner appear to be neither inventions for which they have sought protection, nor inventions originally disclosed in the specification.

Applicants have presented an alternative set of claims for examination. It is believed that these claims are allowable over the art of record.

A notice of allowance is earnestly sought.

Respectfully submitted,

Martin A Hay

Hay, Martin Alexander

Agent for Applicants

Registration No. 39,459

Phone: 011 44 1625 500057

e-mail: martinahay@martin-a-hay.com

Martin A. Hay & Co.,
13 Queen Victoria Street
Macclesfield
Cheshire
SK11 6LP
UNITED KINGDOM

October 24, 2003

RECEIVED
CENTRAL FAX CENTER
OCT 24 2003

OFFICIAL